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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,523	11/07/2001	Jiri Snaidr	235.017US1	9919

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EXAMINER
SAKELARIS, SALLY A

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/008,523	SNAIDR, JIRI	
	Examiner	Art Unit	
	Sally A Sakelaris	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11-2001* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Applicant

This action is in response to Applicant's response to the restriction requirement, filed March 17, 2003. Applicant elected the claims of Group I, claims 1-24 with traverse. The traversal is on the grounds that the search and examination of Groups I and II would not involve a serious burden to the Examiner due to the relatedness of the subject matter of the claims in Groups I and II that allows them to be efficiently and effectively searched and examined in a single application. Applicant is reminded that the kit containing polynucleotides of invention II can be used in a materially different process such as for the RFLP analysis of the *Salmonella* genome, in addition to its use in the process of invention I. It is further maintained that the examiner adhered to the PTO policy concerning restriction practice as defined in *35 U.S.C. 121*, "if two or more independent and distinct inventions are claimed in one application, the commissioner may require the application to be restricted to one of the inventions." The examiner maintains that the inventions are distinct, each from the other and have been restricted appropriately.

The requirement is still deemed proper and is therefore made FINAL. Subsequently, applicant filed a supplemental preliminary amendment on May 19, 2003, wherein; Claims 1, 9 and 10 are amended within the elected claims for examination, claims 1-24. Applicant should note that in their remarks section of the supplemental, filed May 19, 2003, they erred in their assertion that the pending claims are claims 1-29.

Claim Rejections - 35 USC § 112

1. Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 1-24 are indefinite. Claim 1 is drawn to a method of detecting microorganisms in a sample by means of detectable nucleic acid probe molecules. However, the final process step is one of detecting the separated nucleic acid probe molecules. Accordingly, it is unclear as to whether the claim is intended to be limited to methods for detecting the separated nucleic acid probe molecules or for a method of detecting microorganisms in a sample as referred to in the preamble. Applicants should amend the claim to indicate how the step of detecting the separated nucleic acid probe molecules results in the detection of microorganisms in a sample.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 2, 6, 9, 10, 11, 12, 13, 15, 16, 17, 19, 20, 21, 22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Guillot et al.(WO 99/18234, 15 April 1999).

The reference teaches a method of detecting microorganisms in a sample by means of detectable nucleic acid probe molecules comprising the following steps:

a) fixing the microorganisms contained in the sample;(Pg. 3, Pg. 6 lines 10-27)

b) incubating the fixed microorganisms with the detectable nucleic acid probe molecules(Pg 7, lines 3-19) that are complementary to rRNA;(Pg 2-3 esp. 3 lines 18-21)

c) removing nonhybridized nucleic acid probe molecules;(Pgs 7-8 lines 20-3)

d) separating hybridized nucleic acid probe molecules at 100°C without using formamide, and instead through the use of "probe target denaturing agent such as one that will separate duplex DNA/DNA or DNA/RNA"(Pg. 8 lines 5-9 and claim 14)

e) detecting and quantifying the separated nucleic acid probe molecules.(Pg. 8 lines 19-28)

The reference further teaches the above method wherein the detectable nucleic acid probe molecules comprise nucleic acid probe molecules covalently bonded to a detectable marker, such as a radioactive marker(Pg. 8 lines 19-28). In addition the reference teaches the above method for detecting microorganisms wherein the microorganism is a single-cell microorganism and a bacterium(Pgs 4-5 lines 19-14). Guillot et al. teach the above method, wherein the sample is an environmental sample taken from the water, soil and air(Pg. 9 line 6-11); wherein the sample is a food sample taken from drinking water(Pg. 9 line 6); wherein the sample is taken from secretions(ex. urine, vaginal Pg. 9 line 11); wherein the sample is taken from wastewater(""line 7), activated sludge(Pg. 10 line 20), wherein the sample is from industrial effluent("biofilm" as defined on page 15 of specification), organic effluent(Pgs.1, 9, or claim 18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-13, 15-17, and 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guillot et al.(WO 99/18234, 15 April 1999) in view of Roe et al.(DNA isolation and sequencing, 1996), and in further view of Kemp et al.(US Patent 6,090,627).

Guillot et al. teach a method of detecting microorganisms in a sample by means of detectable nucleic acid probe molecules comprising the following steps:

a) fixing the microorganisms contained in the sample;(Pg. 3, Pg. 6 lines 10-27)

b) incubating the fixed microorganisms with the detectable nucleic acid probe molecules(Pg 7, lines 3-19) that are complementary to rRNA;(Pg 2-3 esp. 3 lines 18-21)

c) removing nonhybridized nucleic acid probe molecules;(Pgs 7-8 lines 20-3)

d) separating hybridized nucleic acid probe molecules at 100°C without using formamide, and instead through the use of "probe target denaturing agent such as one that will separate duplex DNA/DNA or DNA/RNA"(Pg. 8 lines 5-9 and claim 14)

e) detecting and quantifying the separated nucleic acid probe molecules.(Pg. 8 lines 19-28)

The reference further teaches the above method wherein the detectable nucleic acid probe molecules comprise nucleic acid probe molecules covalently bonded to a detectable marker, such as a radioactive marker(Pg. 8 lines 19-28). In addition the reference teaches the above method for detecting microorganisms wherein the microorganism is a single-cell microorganism and a bacterium(Pgs 4-5 lines 19-14). Guillot et al. teach the above method, wherein the sample is an environmental sample taken from the water, soil and air(Pg. 9 line 6-11); wherein the sample is a food sample taken from drinking water(Pg. 9 line 6); wherein the sample is taken from secretions(ex.

urine, vaginal Pg. 9 line 11); wherein the sample is taken from wastewater(""line 7), activated sludge(Pg. 10 line 20), wherein the sample is from industrial effluent("biofilm" as defined on page 15 of specification), organic effluent(Pgs.1, 9, or claim 18). Guillot et al. teach the use of any denaturing agent in the method's step d).

Guillot et al. do not exemplify said method of detecting wherein the denaturing agent present in step d), is in a seperation solution of water consisting of 0.001- 1.0 M Tris/HCl, pH 9.0 +/- 2.0 nor do they teach the solution to be incubated at a temperature lower than 100°C or approximately at 80°C.

However, Roe et al. teach this embodiment of water as a denaturing agent in their 10X denaturing buffer consisting of 200mM Tris-HCl, pH 9.5, 1mM EDTA, and 10mM spermidine all in double distilled water. Furthermore, Kemp et al. also teach a denaturing buffer with 20 mM Tris/HCl and a pH of 9.5 being incubated at 70°C.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have practiced the claimed method taught by Guillot et al. of using a "denaturing agent" in step d) wherein the denaturing agent, was contained in the "denaturing buffer" of Roe et al. in order to provide a solution with double distilled water as the denaturing agent in conjunction with the use of Tris/HCl concentrations and the proper pH as exemplified by Kemp et al. with which to denature the hybridized probes for subsequent, accurate quantification as the Tris/Hcl solution is equally as effective means to release the bound probes. With respect to claims 5 and 8 especially, it then would have been further obvious to augment the Tris/HCl concentration and temperature of the separation solution within the limits taught by Roe and Kemp et al. as optimization of conditions for performing a method step are well within the skill of the art. As

discussed in MPEP2144.05(b), "(w)here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 (CCPA 1955).

4. Claims 14, 18, and 24 and 1, 2, 6, 9, 10, 11, 12, 13, 15, 16, 17, 19, 20, 21, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guillot et al.(WO 99/18234, 15 April 1999) in view of Sanders et al.(US Patent 5,888,725)

Guillot et al. teach a method of detecting microorganisms in a sample by means of detectable nucleic acid probe molecules comprising the following steps:

a) fixing the microorganisms contained in the sample;(Pg. 3, Pg. 6 lines 10-27)

b) incubating the fixed microorganisms with the detectable nucleic acid probe molecules(Pg 7, lines 3-19) that are complementary to rRNA;(Pg 2-3 esp. 3 lines 18-21)

c) removing nonhybridized nucleic acid probe molecules;(Pgs 7-8 lines 20-3)

d) separating hybridized nucleic acid probe molecules at 100°C without using formamide, and instead through the use of "probe target denaturing agent such as one that will separate duplex DNA/DNA or DNA/RNA"(Pg. 8 lines 5-9 and claim 14)

e) detecting and quantifying the separated nucleic acid probe molecules.(Pg. 8 lines 19-28)

The reference further teaches the above method wherein the detectable nucleic acid probe molecules comprise nucleic acid probe molecules covalently bonded to a detectable marker, such as a radioactive marker(Pg. 8 lines 19-28). In addition the reference teaches the above method for detecting microorganisms wherein the microorganism is a single-cell microorganism and a bacterium(Pgs 4-5 lines 19-14).

Guillot et al. teach the above method, wherein the sample is an environmental sample taken from the water, soil and air(Pg. 9 line 6-11); wherein the sample is a food sample taken from drinking water(Pg. 9 line 6); wherein the sample is taken from secretions(ex. urine, vaginal Pg. 9 line 11); wherein the sample is taken from wastewater(""line 7), activated sludge(Pg. 10 line 20), wherein the sample is from industrial effluent("biofilm" as defined on page 15 of specification), organic effluent(Pgs.1, 9, or claim 18).

Guillot et al. do not exemplify said method of detecting wherein the microorganism to be detected belongs to the genus *Salmonella* nor the method of detecting wherein the sample is a medicinal one or is taken from a pharmaceutical product.

However, Sanders et al teaches a method for detection, identification and/or quantification of target organisms of specific bacterial genus, based upon the occurrence of nucleotides, specifically for the genus *Salmonella.* The method of the present invention has more readily realized potential for the specific and rapid detection of almost any bacteria in any environmental or forensic sample(foodstuffs, drinking water, pharmaceutical products and diseased tissues in humans, animals, and plants etc.). The reference further teaches that the present invention has been shown to be capable of detection of a single *Salmonella* in a 1 ml sample of milk in under 12 hours.(Column 2 lines 11-19).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have practiced the claimed method taught by Guillot et al. for the detection of microorganism in light of the method taught by Sanders et al. to specifically

detect *Salmonella* in medicinal and pharmaceutical samples, for the expected benefit of a specific and rapid detection system for almost any bacteria in any environment.

5. Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guillot et al.(WO 99/18234, 15 April 1999), in view of Roe et al.(DNA isolation and sequencing, 1996), in further view of Kemp et al.(US Patent 6,090,627), and in even further view of Sanders et al.(US Patent 5,888,725).

Please see above(#3.) for the teachings of Guillot et al.(WO 99/18234, 15 April 1999), in view of Roe et al.(DNA isolation and sequencing, 1996), in further view of Kemp et al.(US Patent 6,090,627).

Guillot et al.(WO 99/18234, 15 April 1999), in view of Roe et al.(DNA isolation and sequencing, 1996), in further view of Kemp et al.(US Patent 6,090,627) do not exemplify this method of detecting wherein the microorganism to be detected belongs to the genus *Salmonella* nor the method of detecting wherein the sample is a medicinal one or is taken from a pharmaceutical product.

However, Sanders et al teaches a method for detection, identification and/or quantification of target organisms of specific bacterial genus, based upon the occurrence of nucleotides, specifically for the genus *Salmonella.* The method of the present invention has more readily realized potential for the specific and rapid detection of almost any bacteria in any environmental or forensic sample(foodstuffs, drinking water, pharmaceutical products and diseased tissues in humans, animals, and plants etc.). The reference further teaches that the present invention has been shown to be capable of

detection of a single *Salmonella* in a 1 ml sample of milk in under 12 hours.(Column 2 lines 11-19).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have practiced the claimed method taught by Guillot et al.(WO 99/18234, 15 April 1999), in view of Roe et al.(DNA isolation and sequencing, 1996), in further view of Kemp et al.(US Patent 6,090,627) for the detection of microorganism in light of the method taught by Sanders et al. to specifically detect *Salmonella* in medicinal and pharmaceutical samples, for the expected benefit of a specific and rapid detection system for almost any bacteria in any environment.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Sally Sakelaris whose telephone number is (703) 306-0284. The examiner can normally be reached on Monday-Thursday from 7:30AM-5:00PM and Friday from 1:00PM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)308-1119. The fax number for the Technology Center is (703)305-3014 or (703)305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703)605-1237.

Sally Sakelaris
6/2/2003

CARLA J. MYERS
PRIMARY EXAMINER